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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/671,005

09/25/2003

Andrzej Fertala

003252-53201

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7590

05/22/2006

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EXAMINER

KOSSON, ROSANNE

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/671,005

Applicant(s)

FERTALA, ANDRZEJ

Examiner

Rosanne Kosson

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3, 7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, claim 3, in the reply filed on June 27, 2005 is acknowledged. The original claims in the non-elected groups, claims 1, 2 and 4-6 have been canceled.

New claims 7 and 8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant states that the new claims read on the elected invention because the protein of claim 3 contains an odd number of collagen domains that are present an odd number of times. But, in the genus of proteins represented in claim 7, 2-5 collagen domains may be present. Thus, they may be present an even or odd number of times. Also, any one of the domains in the first two positions may be any one of D1-D5, and any one of the domains in the last three positions may be any one of D1-D5 or absent. Thus, 1, 2, 3, 4 or 5 different collagen domains may be present, an even number or an odd number of different domains. Consequently, this genus does not read on the claimed invention. X may be 3 or 5, and an odd number of collagen domains may be present, but these are different proteins than that of claim 3, with one exception. X may be 5, and the collagen domains may be D5, D4, D4, D4 and D1. In that case, claims 7 and 8 would be duplicate or redundant claims. Therefore, claims 7 and 8 are withdrawn, and claim 3 is examined on the merits herewith.

Specification

The disclosure is objected to because Table 1 on p. 13 lists amino acid positions whose ranges correspond to Nt, Ct and D1-D5, but no specific protein sequences are referenced. No corresponding literature is provided.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites a protein with seven type II procollagen domains, the N-terminal domain, the D1 domain, the D4 domain, which is present three times consecutively, the D5 domain, and the C-terminal domain. But the specification does not provide the amino acid sequence for any of these domains, nor it refer to and incorporate by reference a reference sequence for a type II procollagen containing all these domains (or different reference sequences containing the different domains). Consequently, because the amino acid sequence of the claimed protein is not known, it cannot be searched in the protein sequence databases. The chemical and structural nature of the claimed protein is undefined, rendering claim 3 indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Art Unit: 1653

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arnold et al., "A cDNA cassette system for the synthesis of recombinant procollagens. Variants of procollagen II lacking a D-period are secreted as triple-helical monomers," Matrix Biol 16:105-116, 1997 (Arnold et al. I) and Arnold et al. "Recombinant procollagen II: deletion of D period segments identifies sequences that are required for helix stabilization and generates a temperature-sensitive N-proteinase cleavage site," J Biol Chem 273(48):31822-31828, 1998 (Arnold et al. II) in view of Fertala et al. (US 6,753,311). Arnold et al. I disclose the gene and protein for type II procollagen and that these contain seven domains- N- and C-termini, D1, D2, D3, D4 and D0.4 (D5). Arnold et al. I also disclose the preparation of a cloning and expression cassette for each domain (see pp. 109-110) and that these seven cassettes can be cloned separately, linked together and cloned or linked and rearranged in novel patterns to produce novel proteins, such as proteins with one of the domains missing or duplicated (see Results on pp. 111 and 112). The novel proteins are secreted in a triple-helical conformation, similarly to the native protein, allowing for their use in mapping specific binding sites and in experiments on cell binding, spreading and signaling through integrin and other receptors (see p. 114, right col.). Arnold et al. II disclose the same cloning and expression system for type II procollagen using the seven polynucleotide cassettes, each encoding a different domain (see p. 31823 and Fig. 1 on p. 31824). Arnold et al. II also disclose that the D1, D5 (D0.4) and D4 domains are critical for thermostability and retention of proper folding, whereas the D2 and D3 domains are not critical (see Discussion on pp. 31826 and 31827). Arnold et al. I and II do not disclose the specific sequence of the protein of claim 3. But they teach that the seven parts of the type II procollagen gene may be linked together and rearranged as desired to produce any novel protein containing

Art Unit: 1653

at least one of these parts. The novel protein may have one or more parts missing, or one or more parts duplicated.

Fertala et al. disclose that the D4 domain of type II procollagen has been demonstrated to promote attachment, growth and spreading of chondrocytes on type II procollagen used as a cell culture scaffold. Better results on scaffolds are achieved when the D4 domain is present uniformly through a cell culture matrix (see col. 5, lines 13-35).

One of ordinary skill in the art at the time that the invention was made would have been motivated to modify native type II procollagen for culturing cells as disclosed by Arnold et al. I and Fertala et al., deleting the non-critical domains and replicating the domains with beneficial properties, because Arnold et al. I teach that the termini, D1, D4 and D5 domains must be maintained for structural stability, while the D2 and D3 domains need not be retained. Fertala et al. teach that the D4 domain of a collagen scaffold is critical for proliferation and attachment of cells in culture and should be present uniformly throughout. One of ordinary skill in the art would have been motivated to delete the non-critical domains and replicate the critical domains, because Arnold et al. II disclose that novel proteins containing one or more of their seven building blocks and having selected desired properties may be designed and prepared by linking together a selected permutation of corresponding DNA cassettes and cloning and expressing the protein. Any domain may be absent or present multiple times. The artisan of ordinary skill would have recognized that replacing the non-critical domains with domains that impart thermal stability and promote cell binding and cell proliferation would have produced a type II procollagen scaffold with superior cell culture properties. The selection of a specific protein sequence, i.e., the specific arrangement of the building block cassettes is a result-effective parameter which was routinely optimized by one of ordinary skill in the art of molecular biology. Thus, the variations in Applicant's claimed sequence with respect to the prior art clearly

Art Unit: 1653

would have been obvious at the time of Applicant's invention, the optimization of this sequence being well within the capabilities of the artisan of ordinary skill at the time of Applicant's invention. Therefore, a holding of obviousness is required.

Double Patenting- Obviousness Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 3 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 4 of U.S. Patent No. 6,753,311. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of issued patent are drawn to a type II collagen scaffold comprising the D4 domain, while the instant claim is drawn to a type II collagen-like protein comprising the D4 domain. The instant claimed protein is the material of which the patented scaffold is made. Polymers of the instant claimed protein naturally form fibrils and three-dimensional matrices and may be electrospun to form fibers and scaffolds (see col. 3, lines 44-64, of the issued patent). The important cell culture properties of the D4 domain are disclosed (see col. 5, lines 13-35, of the instant patent). The procollagen II DNA cassette system for producing novel, engineered collagen-like proteins is also disclosed (see col. 7, lines 27-37). The claimed protein is an

Art Unit: 1653

obvious engineered collagen-like protein that may be produced by using the aforementioned cassette system. Therefore, an obviousness type double patenting rejection is required.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

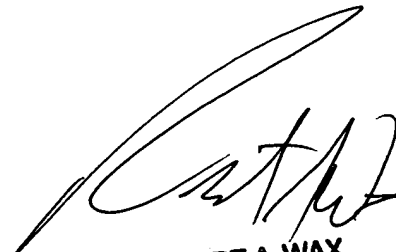
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1653

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner
Art Unit 1653

rk/2006-05-05



ROBERT A. WAX
PRIMARY EXAMINER